EPA/OPP MICROBIOLOGY LABORATORY ESC, Ft. Meade, MD

Standard Operating Procedure for

Verification of Volume Dispensed and Maintenance of Oxford Automatic Dispensor and Hamilton Microlab 500

SOP Number: EQ-08-03

Date Revised: 06-29-05

Prepared By:		Date:	_/	/
	Print Name:			
Reviewed By:		Date:	_/	_/
	Print Name:			
	Technical Staff			
		Date:	_/	/
	Print Name:			
	QA Officer			
Approved By:		Date:	_/	/
	Print Name:			
	Branch Chief	_		
Date Issued:	//			
Withdrawn By	:	Date:	_/	_/
Controlled Cop	oy No.:			

TABLE OF CONTENTS

	<u>Contents</u>	Page Number
1.0	SCOPE AND APPLICATION	2
2.0	DEFINITIONS	2
3.0	HEALTH AND SAFETY	2
4.0	CAUTIONS	2
5.0	INTERFERENCES.	3
6.0	PERSONNEL QUALIFICATIONS	3
7.0	SPECIAL APPARATUS AND MATERIALS	3
8.0	INSTRUMENT OR METHOD CALIBRATION	4
9.0	SAMPLE HANDLING AND STORAGE	4
10.0	PROCEDURE AND ANALYSIS	4
11.0	DATA ANALYSIS/CALCULATIONS	5
12.0	DATA MANAGEMENT/RECORDS MANAGEMENT	6
13.0	QUALITY CONTROL	6
14.0	NONCONFORMANCE AND CORRECTIVE ACTION	6
15.0	REFERENCES.	6
16.0	FORMS AND DATA SHEETS	6

1.0 <u>SCOPE AND APPLICATION</u>:

1.1 This protocol describes the quality control requirements for the Oxford Automatic Dispensor and Hamilton Microlab 500 (see ref. 15.1 and 15.2).

2.0 DEFINITIONS:

- 2.1 Prime = To make an instrument ready for operation by running fluid through the fluid path (tubing, valves and syringes) of an instrument to remove all bubbles and air gaps.
- 2.2 Target Volume = Required volume of media.
- 3.0 HEALTH AND SAFETY: Not applicable
- 4.0 CAUTIONS:
 - 4.1 Oxford Automatic Dispensor
 - 4.1.1 The instrument should be primed prior to use and between fluid changes, as explained in the User's Manual (see ref. 15.1). Briefly, before using the instrument and after each use (or when changing media), at least one liter of de-ionized water must be dispensed through the system.
 - 4.1.2 Always start dispensing high volumes at low speed.
 - 4.1.3 Always check hose connections before operating the machine.
 - 4.2 Hamilton Microlab 500 System
 - 4.2.1 Prime the instrument before using for the first time, at the start of a workday and between fluid changes, as explained in sections
 3 8 of User's Manual (see ref. 15.2). Briefly, the tubing and syringes should be purged and primed by running 1 L of deionized water through them.
 - 4.2.2 Clean the instrument periodically by flushing the tubing and syringes with 70% ethanol or with a chlorine bleach and de-ionized water solution (one part household bleach and nine parts de-ionized water). Rinse tubing with de-ionized water. Let approximately 1 L of de-ionized water run through the tubing.

- 4.2.3 Leave the syringes and tubing filled with de-ionized water. Do not operate the syringes dry, as this may cause excessive wear on the syringes and valves.
- 4.2.4 Avoid using caustic or acidic cleaning solutions.

5.0 <u>INTERFERENCES</u>:

- 5.1 Oxford Automatic Dispensor
 - 5.1.1 High volumes or viscous fluids dispensed at high speed will result in extremely high discharge velocities and valve pressures that can damage the valve.
 - 5.1.2 Calibration may be altered if the unit is operated at a speed setting other than the range specified (speed knob at 6-7).
- 5.2 Hamilton Microlab 500 System: None.

6.0 PERSONNEL QUALIFICATIONS:

6.1 Personnel are required to be knowledgeable of the procedures in this SOP.

7.0 SPECIAL APPARATUS AND MATERIALS:

- 7.1 Oxford Automatic Dispensor
 - 7.1.1 Curtin Matheson, Product No. 8885-047004, Serial Number 10012369. Manufacturer claims precision of 0.5%. With polypropylene accessory pack, Catalog No. 387-894, instrument can dispense volumes from 2 mL to 20 mL.
 - 7.1.3 100 mL volumetric flasks.
- 7.2 Hamilton Microlab 500 System
 - 7.2.1 Microlab 540 B, Serial No. MD92JMO868, Catalog No. 35892: The instrument can dispense volumes from 2.5 mL to 50 mL.
 - 7.2.2 Controller Unit and cord, Catalog No. 35893

- 7.2.3 Dual hand probe, Catalog No. 35767
- 7.2.4 Syringes: Size 25 mL, Model No. 1025 TLL, Catalog No. 82521
- 7.2.5 Two 50 mL Volumetric flasks

8.0 INSTRUMENT OR METHOD CALIBRATION:

- 8.1 The instruments are calibrated at a setting higher than the target volume to account for loss of fluid due to autoclaving/evaporation.
- 9.0 SAMPLE HANDLING AND STORAGE: Not applicable
- 10.0 PROCEDURE AND ANALYSIS:
 - 10.1 Oxford Automatic Dispensor
 - 10.1.1 The instrument is set to deliver 10.3 mL quantities of liquid.

 However, in the event that the instrument is set to deliver other than 10.3 mL, the verification of volume would be performed on the specific target volume prior to use.
 - 10.1.2 On a monthly basis, the volume dispensed is verified. Ten 10.3 mL aliquots of de-ionized water are dispensed into a 100 mL volumetric flask. The instrument will be calibrated at a speed between 6 and 7. Speed can be adjusted using the speed control knob. If the amount of liquid dispensed is above the 100 mL volume mark, use a 5 mL serological pipette to determine the volume that is greater than 100 mL. If the amount of liquid dispensed is below the 100 mL volume mark, use a 5 mL serological pipette to determine the volume that is less than 100 mL by adding the appropriate volume to bring the level to the 100 mL volume mark. Calculate the volume dispensed and percent error. The error must be less than 5% or the machine must be re-calibrated (see ref. 15.1).
 - 10.1.3 The instrument is cleaned periodically by disassembling the dispensing parts and soaking them in Alconox detergent. The parts are subsequently rinsed thoroughly with tap water and with deionized water prior to reassembly.
 - 10.2 Hamilton Microlab 500 System

- 10.2.1 Currently the instrument has been programmed to deliver 9.4 mL of liquid from each probe of the dual hand probe (see section 7.2.3). However, in the event that the unit is set to deliver a volume other than 9.4 mL, the verification of volume must be performed on the specific target volume prior to use.
- 10.2.2 The volume dispensed is verified quarterly.
- 10.2.3 To verify volume, dispense ten 9.4 mL aliquots of de-ionized water into 2 containers (five 9.4 mL aliquots from each probe of the dual hand probe). Pour contents into two 50 mL volumetric flasks to measure the quantities. If the amount of liquid dispensed is above the volume mark(s), use a 5 mL serological pipette to determine the volume that is greater than 50 mL by removing the amount necessary to bring the volume to the 50 mL volume mark. If the amount of liquid dispensed is below the volume mark(s), use a 5 mL serological pipette to determine the volume that is less than 50 mL by adding the appropriate volume to bring the level to the 50 mL volume mark. Calculate the volume dispensed and percent volume. The error must be less than 5% or the machine must be reprogrammed.

11.0 <u>DATA ANALYSIS/CALCULATIONS</u>:

- 11.1 Oxford Automatic Dispensor
 - 11.1.1 Calculate percent error for the amount of liquid dispensed. The percent error is determined using the formula:

- 11.2 Hamilton Microlab 500 System
 - 11.2.1 Calculate percent error for the amount of liquid dispensed. The percent error is determined using the formula:

SOP No. EQ-08-03 Date Revised 06-29-05 Page 6 of 8

12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:

12.1 The data will be recorded promptly, legibly and in indelible ink on the appropriate forms namely Oxford Automatic Dispensor Maintenance Record Form or Hamilton Microlab 500 Record Form. Completed forms are archived in notebooks kept in secured files in the File Room D217. Only authorized personnel have access to the secured files. Archived data is subject to OPP's official retention schedule contained in SOP ADM-03, Records and Archives.

13.0 **QUALITY CONTROL**:

13.1 For quality control purposes, calibration check information is documented on the appropriate record form (see 16.1).

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

14.1 Any deviation in the protocol is documented and kept in laboratory records. The instruments are re-calibrated, as indicated in the manufacturers' instruction manuals, if the percent error is >5% (see ref. 15.1 and 15.2).

15.0 REFERENCES:

- 15.1 Oxford Automatic Dispensor Instructions.
- 15.2 User's Manual: Hamilton Microlab 500.

16.0 FORMS AND DATA SHEETS:

- 16.1 Oxford Automatic Dispensor Record Form.
- 16.2 Hamilton Microlab 500 Record Form.

SOP No. EQ-08-03 Date Revised 06-29-05 Page 7 of 8

Verification of Volume of Oxford Automatic Dispensor Record OPP Microbiology Laboratory

Date/ Initials	Number of Units Dispensed	Dispensed Volume`	Liquid Added/ Removed	Total Volume Measured	% Error	Corrective Action/Comments

SOP No. EQ-08-03 Date Revised 06-29-05 Page 8 of 8

Verification of Volume of Hamilton Microlab 500 Record OPP Microbiology Laboratory

Date/ Initials	Number of Units Dispensed	Dispensed Volume	Liquid Added/ Removed	Total Volume Measured	% Error	Corrective Action/Comments
	_		_		_	
	_		_		_	